

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in March 2013.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-541

Trade Name: Gonabreed™
Pioneer: Cystorelin®
Ingredients: Gonadorelin acetate
Sponsor: Parnell Technologies Pty. Ltd.
Approval Date: January 17, 2013
Status: Rx
Route: Cystic ovary indication: Intravenous or intramuscular injection
Estrous synchrony indication: Intramuscular injection
Species: Cystic ovary indication: Dairy cattle
Estrous synchrony indication: Lactating dairy cows and beef cows
Drug Form: Injectable solution
Concentration: 100 mcg gonadorelin/mL as gonadorelin acetate
Indications: For the treatment of ovarian follicular cysts in dairy cattle. For use with cloprostenol sodium to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows and beef cows.
Exclusivity: 3 years

21 CFR 522.1073

78 FR 17866-17868

Sponsor Change

NADA Number: 141-210

Previous: RMS Laboratories, Inc.

New Sponsor: Virbac AH, Inc.

Drug Labeler Code: 051311

21 CFR 524.2482

78 FR 17866-17868

ANADA Number: 200-176

Previous: Teva Animal Health, Inc.

New Sponsor: Cross Vetpharm Group Ltd.

Drug Labeler Code: 061623

21 CFR 522.1870

78 FR 17866-17868

(A)NADA Numbers: 6-391, 6-677, 7-087, 33-157, 40-040, 45-416, 48-287, 55-002, 65-110, 65-498, 91-818, 93-483, 94-170, 99-169, 119-142, 123-815, 124-241, 128-089, 140-270, 141-070, 141-245, 200-042, 200-068, 200-069, 200-108, 200-118, 200-123, 200-124, 200-126, 200-137, 200-147, 200-153, 200-162, 200-174, 200-177, 200-178, 200-181, 200-192, 200-193, 200-202, 200-219, 200-228, 200-230, 200-246, 200-248, 200-253, 200-254, 200-256, 200-265, 200-286, 200-287, 200-293, 200-297, 200-298, 200-319, 200-322,

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200–342, 200–351, 200–360, 200–365, 200–382, 200–389, 200–408, 200–463

Previous: Teva Animal Health, Inc.

New Sponsor: Bayer HealthCare LLC, Animal Health Division

Drug Labeler Code: 000859

21 CFR 510.600, 520.100, 520.446, 520.447, 520.1010, 520.1044b, 520.1192, 520.1193, 520.1195, 520.1484, 520.1720a, 520.1870, 520.2043, 520.2044, 520.2123c, 520.2220a, 520.2260b, 520.2325a, 520.2455, 522.23, 522.56, 522.246, 522.390, 522.540, 522.810, 522.1010, 522.1044, 522.1066, 522.1086, 522.1182, 522.1192, 522.1222a, 522.1260, 522.1660a, 522.1662a, 522.1680, 522.1696a, 522.1696b, 522.1720, 522.2005, 522.2120, 522.2220, 522.2615, 524.1044g, 524.1193, 529.56, 529.1044a, 558.586 78 FR 17595-17598

Withdrawal of Approval

NADA Number: 009–252

Sponsor: Mid-Continent Agrimarketing, Inc.
Trade Name: Fumidil B
Ingredients: Bicyclohexylammonium fumagillin

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 520.182 78 FR 14667-14669

NADA Number: 034–601

Sponsor: G.D. Searle LLC, Pharmacia Corp.
Trade Name: Synchro-Mate®
Ingredients: Flurogestone acetate

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 529.1003 78 FR 14667-14669

NADA Number: 039–284

Sponsor: Swisher Feed Division, William Davies Co., Inc.
Trade Name: Swisher Super Broiler 300–108
Ingredients: Amprolium, ethopabate, bacitracin zinc, and roxarsone

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 558.58 78 FR 14667-14669

NADA Number: 040–920

Sponsor: Honeggers and Co., Inc.
Trade Name: Chick Grower Developer Fortified
Ingredients: Amprolium

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

Not codified 78 FR 14667-14669

NADA Number: 094–223

Sponsor: K.C. Pharmacal, Inc.

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The following corrections or additions to the list were published in the Federal Register in March 2013.

Trade Name: Canine Worm Caps
Ingredients: n-butyl chloride

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 520.260 78 FR 14667-14669

NADA Number: 098–429

Sponsor: J. C. Feed Mills
Trade Name: Medic-Meal-T Premix
Ingredients: Tylosin phosphate

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 558.625 78 FR 14667-14669

NADA Number: 098–639

Sponsor: Bioproducts, Inc.
Trade Name: Tylan® Sulfa-G
Ingredients: Tylosin phosphate and sulfamethazine

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 558.630 78 FR 14667-14669

NADA Number: 106–507

Sponsor: Custom Feed Blenders Corp.
Trade Name: Tylan® 10
Ingredients: Tylosin phosphate

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 558.625 78 FR 14667-14669

NADA Number: 110–044

Sponsor: Peavey Co.
Trade Name: Peavy Pro-Tone Plus Pak GF T-1
Ingredients: Tylosin phosphate

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 558.625 78 FR 14667-14669

NADA Number: 117–688

Sponsor: Texas Vitamin Co.
Trade Name: Dichlorophene and Toluene Capsules
Ingredients: Dichlorophene and toluene

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 520.580 78 FR 14667-14669

NADA Number: 120–614

Sponsor: Webel Feeds, Inc.
Trade Name: Tylan® Sulfa-G
Ingredients: Tylosin phosphate and sulfamethazine

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

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21 CFR 558.630

78 FR 14667-14669

NADA Number: 120–671

Sponsor: K.C. Pharmacal, Inc.
Trade Name: Pet-Worm-Caps
Ingredients: Dichlorophene and toluene

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 520.580

78 FR 14667-14669

NADA Number: 121–147

Sponsor: Ag-Mark, Inc.
Trade Name: Nutra-Mix Tylan®
Ingredients: Tylosin phosphate

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 558.625

78 FR 14667-14669

NADA Number: 122–522

Sponsor: Custom Feed Blenders Corp.
Trade Name: Tylan® Sulfa-G
Ingredients: Tylosin phosphate and sulfamethazine

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 558.630

78 FR 14667-14669

NADA Number: 124–391

Sponsor: Ag-Mark, Inc.
Trade Name: Nutra-Mix Tylan®-Sulfa Premixes
Ingredients: Tylosin phosphate and sulfamethazine

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 558.630

78 FR 14667-14669

NADA Number: 127–195

Sponsor: I.M.S. Inc.
Trade Name: Tylan® 10
Ingredients: Tylosin phosphate

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 558.625

78 FR 14667-14669

NADA Number: 129–415

Sponsor: Custom Feed Blenders Corp.
Trade Name: Custom Ban Wormer 9.6 Banminth
Ingredients: Pyrantel tartrate

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 558.485

78 FR 14667-14669

NADA Number: 130–092

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The following corrections or additions to the list were published in the Federal Register in March 2013.

Sponsor: Vetem, S.p.A.
Trade Name: Alfavet™
Ingredients: Alfaprostol

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 522.46

78 FR 14667-14669

NADA Number: 141–101

Sponsor: BioScience Division of Milk Specialties Co.
Trade Name: Preempt™
Ingredients: Competitive exclusion culture

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 529.469

78 FR 14667-14669

ANADA Number: 200–187

Sponsor: Marsam Pharmaceuticals, LLC
Trade Name: Isoflurane, USP
Ingredients: Isoflurane

This product is withdrawn for lack of compliance with reporting requirements in 21 CFR 514.80.

21 CFR 529.1186

78 FR 14667-14669